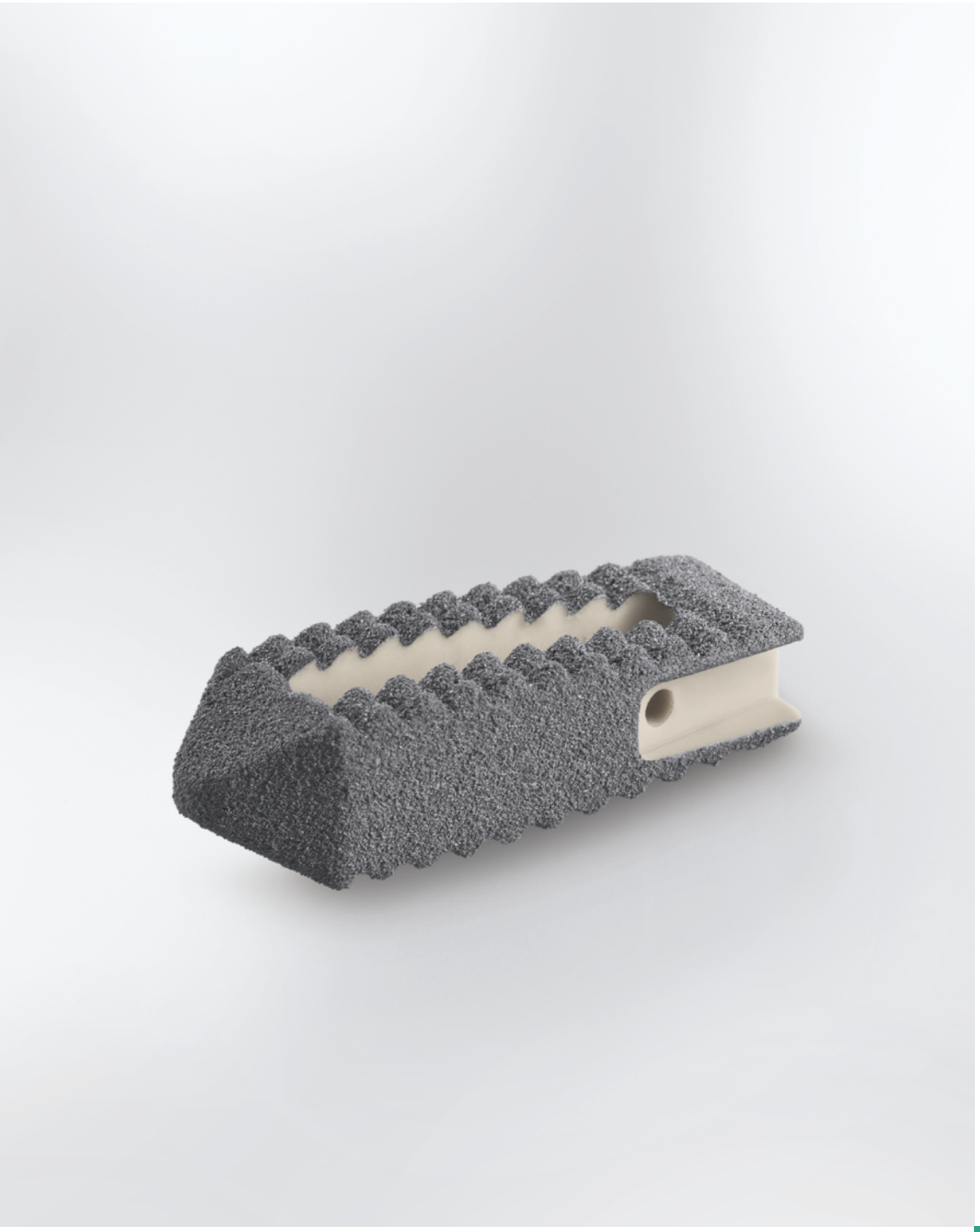
B BRAUN
SHARING EXPERTISE



SPINE SURGERY

AESCULAP® PROSPACE® XP

POSTERIOR LUMBAR INTERBODY FUSION SYSTEM

SURGICAL MANUAL

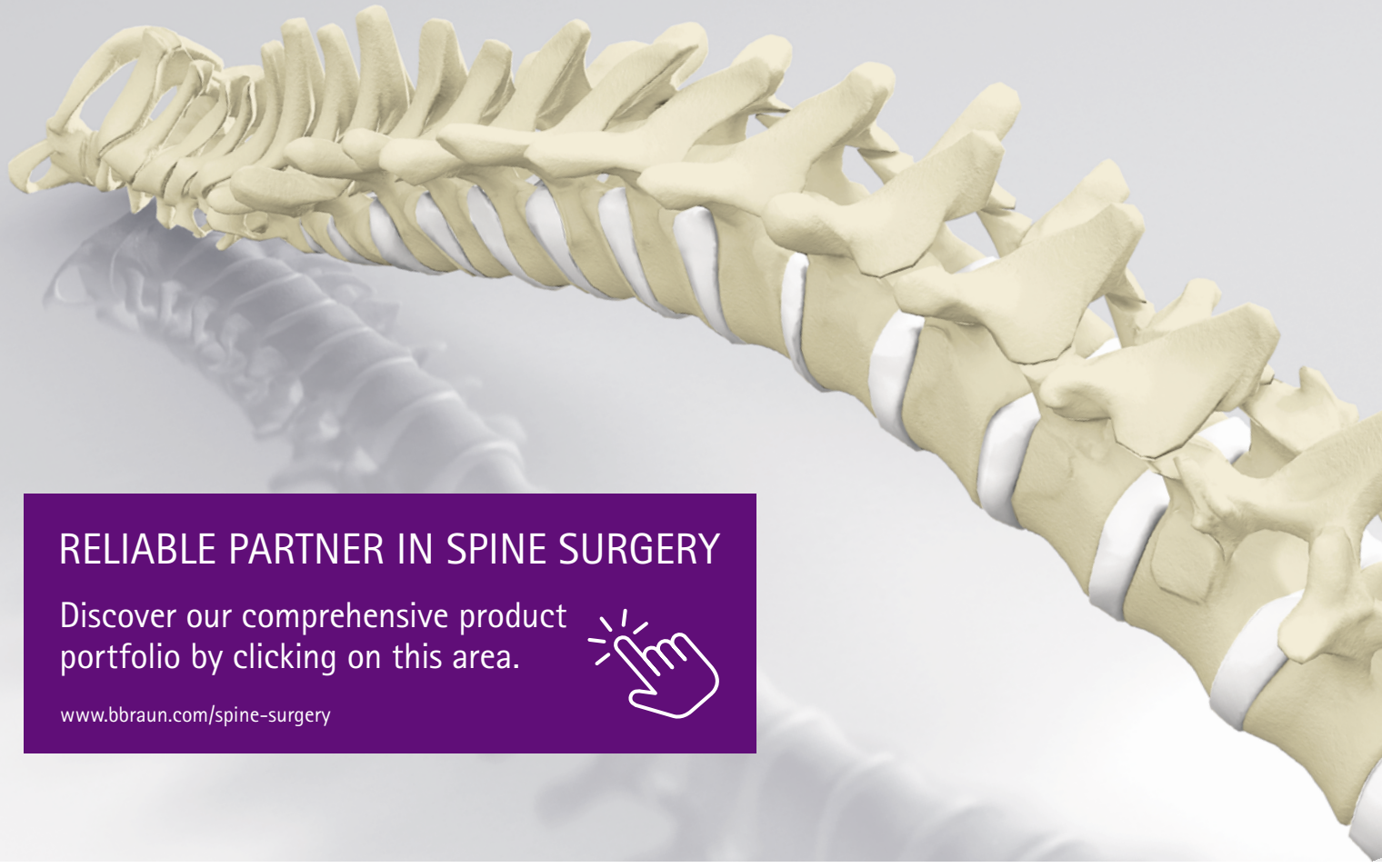
AESCULAP® THORACOLUMBAR SPINE

PROTECTING AND PRESERVING SPINAL STABILITY

Modern lifestyle has resulted in increasing physical inactivity among people all over the world. Of the many medical problems associated with this, spinal disorders are among the most critical. This is even more significant as the spinal column is one of the most important structures in the human body.

It supports and stabilizes the upper body and is the center of our musculoskeletal system, which gives the body movement. Our work in the field of spine surgery is dedicated to protecting the spinal column and preserving its stability. We support spine surgeons with durable, reliable products and partner services for reliable procedures and good clinical outcomes (1-7).

Our philosophy of sharing expertise with healthcare professionals and patients allows us to develop innovative implant and instrument systems that help to preserve stability and stabilize the cervical and thoracolumbar spine.



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AESCULAP® PROSPACE® XP

CONTENT

AESCULAP® PROSPACE® XP

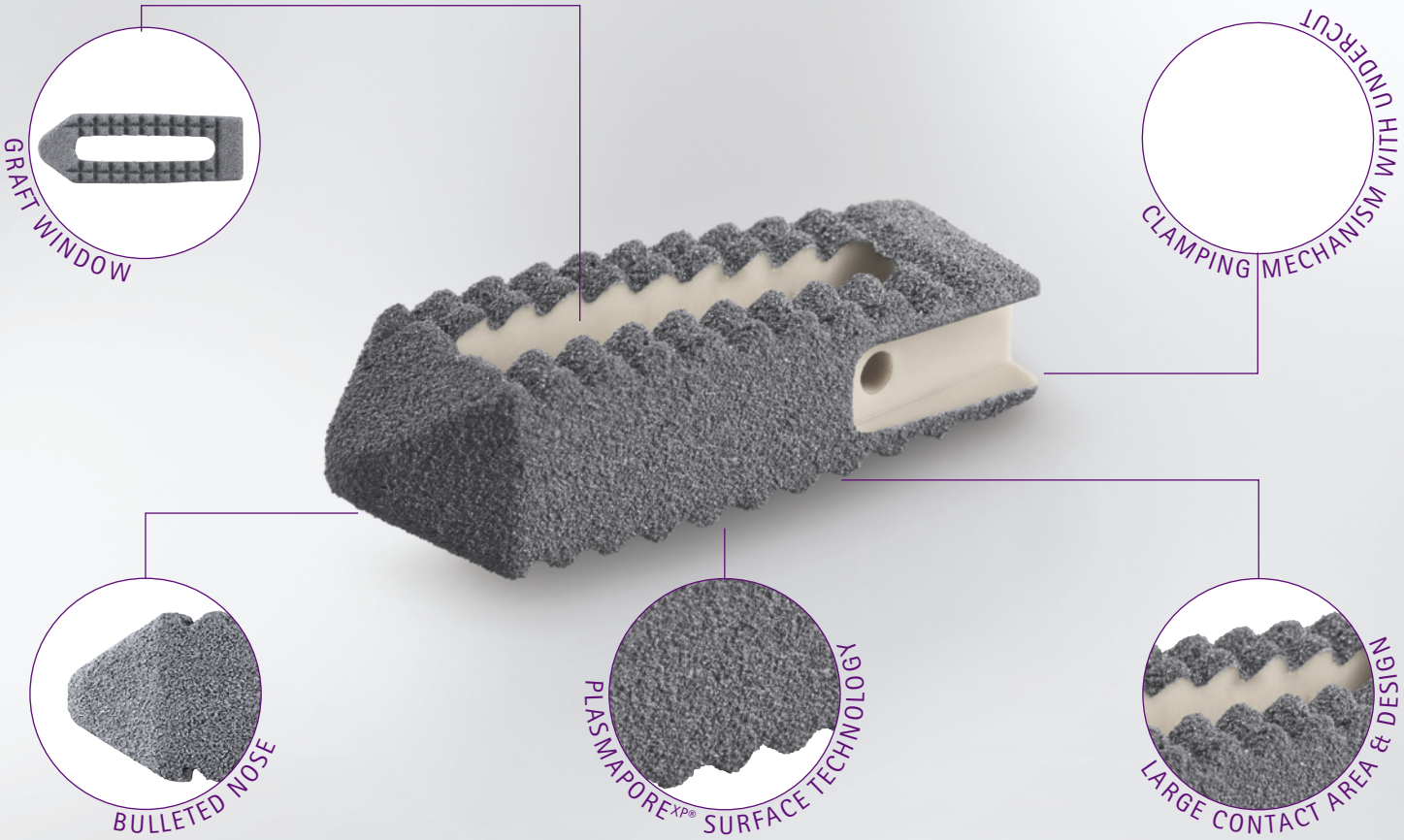
PHILOSOPHY

PROSPACE® XP implants are used for the stabilization of the lumbar and thoracic spine through posterior approach, monosegmental and multisegmental.

Always implant two implants per layer (PLIF technique). Always use PROSPACE® XP implants in conjunction with an internal fixator.

PROSPACE® XP IS DESIGNED TO DELIVER

- PRIMARY STABILITY (8).
- RESTORATION OF THE NATURAL DISC HEIGHT AND LORDOSIS.



AESCULAP® XP
THE CHOICE OF EXPERTS

IMPLANT MATERIAL

PROSPACE® XP - PLASMAPORE XP®

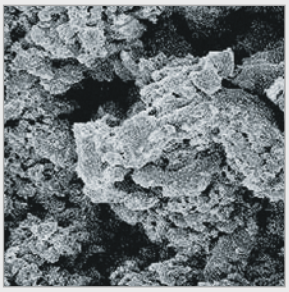


Fig. 1

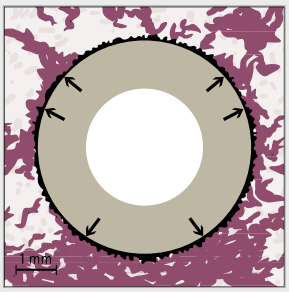


Fig. 2

COMBINING MATERIAL ADVANTAGES

The core of the implant is biocompatible PEEK-OPTIMA®. PEEK stands for PolyEtherEtherKetone. PEEK-OPTIMA® polymer complies with ISO 10993-1, USP Class VI and ASTM F2026 for use as a medical implant material. The use of the PEEK-OPTIMA® material has several advantages, as its properties include radiolucency, high mechanical strength, high fatigue resistance, a low wear factor and biocompatibility (9-14).
The core is mantled with the proven PLASMAPORE XP® coating to increase the contact area between implant and endplate (15). PLASMAPORE XP® is an osteoconductive pure titanium coating (Ti/ISO 5832-2) which enables bone ingrowth due to its balanced relationship between pore depth, porosity and roughness (15). The coating allows for clear visualization of implant contours during intra and post operative imaging.

AIM OF THE PLASMAPORE XP® COATING

- **Primary Stability**
  The increased surface roughness of the PLASMAPORE XP® coating contributes to the primary stability of the motion segment (Fig. 1) (15-16).
- **Secondary Stability**
  Bone growth into the coating is enabled due to the supportive features of PLASMAPORE XP®, which leads to bone fusion between the adjacent vertebras with the implant (15-16) (Fig. 2).

IMPLANT FEATURES

PROSPACE® XP - PLASMAPORE XP®

Fig. 3

Fig. 4

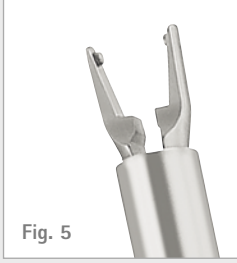


Fig. 5

IMAGING PROPERTIES

- PLASMAPORE XP® allows for clear visualization of implant contours under X-ray (17).
- X-ray pins facilitating implant positioning and localization.
- Allows for assessment of the bone structure and progress towards bone fusion (18)

IMPLANT DESIGN

- Anatomical shape and bulleted nose facilitate implantation and fit.
- Serrated profile for a high primary stability (Fig. 4) (8).
- Option of filling with bone or bone substitute to enhance bone bridging.
- Clamping mechanism for connection with inserter (Fig. 4).

IMPLANT VARIETY

- Adequate range of sizes to enable the choice of implant size to fit the patient.

INSTRUMENT DESIGN

- Specifically designed and clearly arranged instruments.
- Inserter with clamping mechanism (Fig. 5).

AESCULAP® PROSPACE® XP

B | SURGICAL MANUAL

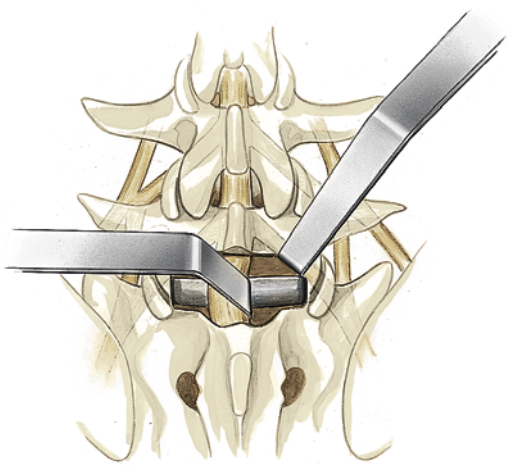


Fig. 1

B.1. BONE RESECTION

- Using an osteotome and a KERRISON bone punch the bone resection is performed to get access to the intervertebral space.

B.2. REVEALING THE DISC SPACE

- The dura and upper nerve root are carefully retracted in the desired direction using the nerve root retractors (Fig. 1).
- In order to make room for the insertion of the distractor, resection of disc material is now carried out using rongeurs and forceps.

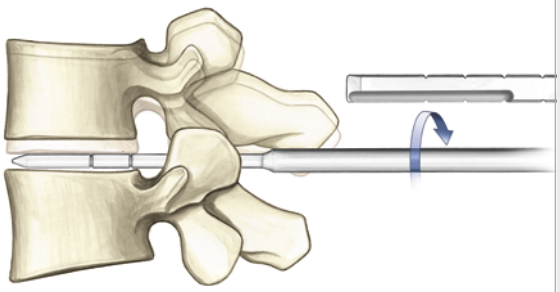


Fig. 2

B.3. RESTORATION OF DISC HEIGHT

- The desired distraction can be set using the distractors, available in heights from 7-13 mm in 1 mm increments (Fig. 2). The distractors are inserted one after the other alternating the side of the disc until the desired distraction is obtained.

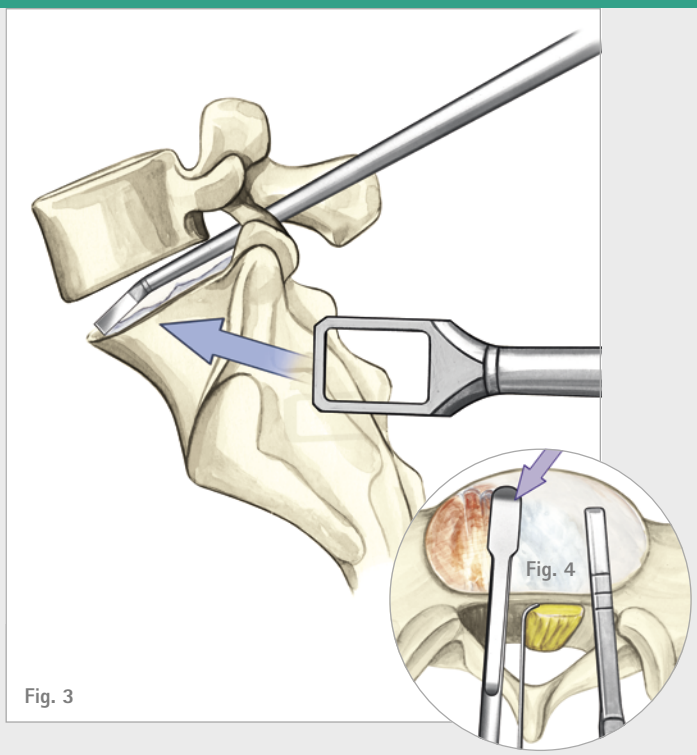


Fig. 3

B.4. CLEANING OF THE INTERVERTEBRAL SPACE

- The disc space is cleared using rongeurs and curettes (Fig. 3).
- The bone rasp is used to refresh the cartilaginous endplates. Alternatively, the curette can be used (Fig. 4).

INFORMATION

Make certain that the endplates of the neighboring vertebral bodies are not weakened, in order to minimize the risk of migration.

Make certain that the implant bed is properly prepared to avoid damage to the implant when it is driven in.

Use the nerve root retractors to protect the dura during insertion.

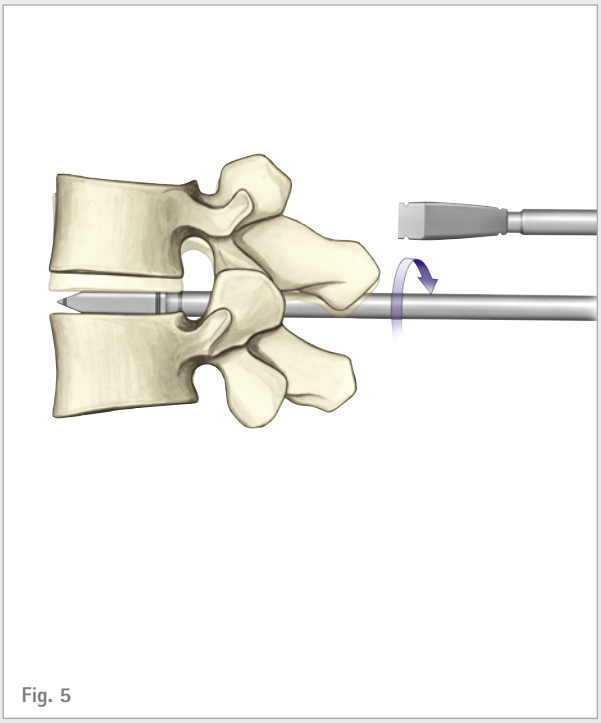


Fig. 5

B.5. DETERMINATION OF IMPLANT SIZE

- Trials are available in 5° and corresponding to the implant height. The trials measure 26 mm in length and indicate the length 22 mm by a laser marking. Starting with the smallest size the trials are inserted horizontally and rotated clockwise. Stepwise the next heights are inserted until the required distraction has been achieved (Fig. 5).

INFORMATION

The trials are essential to ensure the correct implant size to be used.

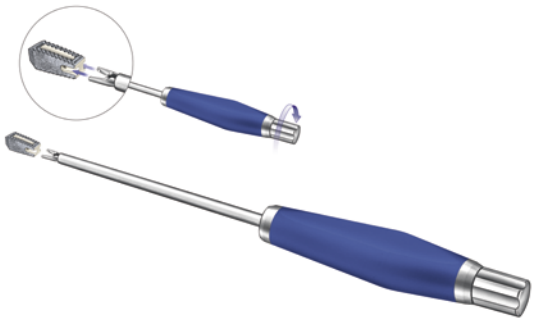


Fig. 1

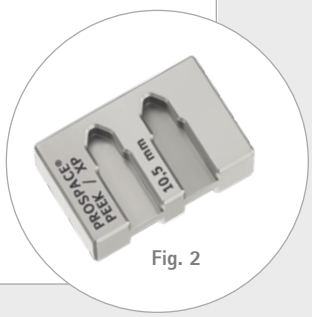


Fig. 2

B.6. INSERTION OF PROSPACE® XP

- After filling the PROSPACE® XP implant with bone graft or bone substitute the implant is clamped to the inserter and introduced into the disc space (Fig. 1/2).

INFORMATION

- Do not use force during filling to avoid implant damaging.
- Mount the implant on the insertion instrument hand-tight as far as it will go.
- When inserting the implant into the intervertebral space, avoid canting and levering, and take care to maintain an alignment parallel to the endplate.
- Do not use excessive force when mounting or implanting the implant.

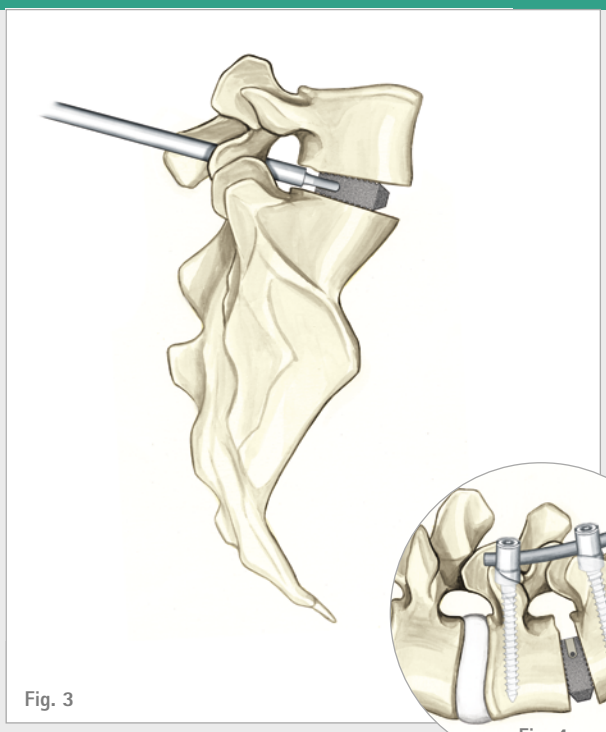


Fig. 3

Fig. 4

B.7. INSERTION ON THE CONTRA-LATERAL SIDE

- The described operative steps are now repeated for the contra-lateral side. Bone material can be packed between both implants (Fig. 3).
- The implants get jammed by release of distraction as well as by compression with the posterior instrumentation.
- X-ray control to verify the position of the implants.

B.8. POSTERIOR STABILIZATION

- Additional posterior stabilization of the motion segment (e. g. using AESCULAP® Ennovate®) should be performed (Fig. 4).
- Subsequent segmental compression with posterior instrumentation allows loading of the anterior column and restoration of sagittal alignment.
- Final X-ray.

For further details on Ennovate® Spinal System please visit www.bbraun.com/ennovate

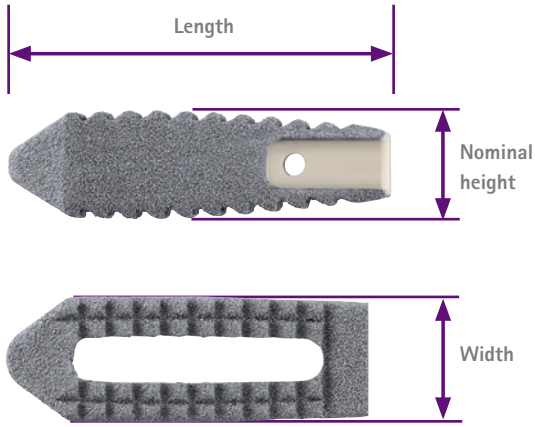
INFORMATION

Thoracolumbar pedicle screw system shown in images is the AESCULAP® S4® Spinal System.

AESCULAP® PROSPACE® XP

C | IMPLANT & INSTRUMENT OVERVIEW

PROSPACE® XP IMPLANTS



Article No.	Size (Length x Width x Height)	Angle
SO107P	22 x 8.5 x 7 mm	0°
SO108P	22 x 8.5 x 8 mm	0°
SO109P	22 x 8.5 x 9 mm	0°
SO110P	22 x 8.5 x 10 mm	0°
SO111P	22 x 8.5 x 11 mm	0°
SO117P	22 x 8.5 x 7 mm	5°
SO118P	22 x 8.5 x 8 mm	5°
SO119P	22 x 8.5 x 9 mm	5°
SO120P	22 x 8.5 x 10 mm	5°
SO121P	22 x 8.5 x 11 mm	5°
SO128P	22 x 8.5 x 8 mm	8°
SO129P	22 x 8.5 x 9 mm	8°
SO130P	22 x 8.5 x 10 mm	8°
SO131P	22 x 8.5 x 11 mm	8°
SO137P	26 x 8.5 x 7 mm	0°
SO138P	26 x 8.5 x 8 mm	0°
SO139P	26 x 8.5 x 9 mm	0°
SO147P	26 x 8.5 x 7 mm	5°
SO148P	26 x 8.5 x 8 mm	5°
SO149P	26 x 8.5 x 9 mm	5°
SO158P	26 x 8.5 x 8 mm	8°
SO159P	26 x 8.5 x 9 mm	8°

All PROSPACE® XP implants are single sterile packed.

Article No.	Size (Length x Width x Height)	Angle
SO410P	22 x 10.5 x 10 mm	0°
SO411P	22 x 10.5 x 11 mm	0°
SO412P	22 x 10.5 x 12 mm	0°
SO413P	22 x 10.5 x 13 mm	0°
SO420P	22 x 10.5 x 10 mm	5°
SO421P	22 x 10.5 x 11 mm	5°
SO422P	22 x 10.5 x 12 mm	5°
SO423P	22 x 10.5 x 13 mm	5°
SO430P	22 x 10.5 x 10 mm	8°
SO431P	22 x 10.5 x 11 mm	8°
SO432P	22 x 10.5 x 12 mm	8°
SO433P	22 x 10.5 x 13 mm	8°
SO440P	26 x 10.5 x 10 mm	0°
SO441P	26 x 10.5 x 11 mm	0°
SO442P	26 x 10.5 x 12 mm	0°
SO443P	26 x 10.5 x 13 mm	0°
SO450P	26 x 10.5 x 10 mm	5°
SO451P	26 x 10.5 x 11 mm	5°
SO452P	26 x 10.5 x 12 mm	5°
SO453P	26 x 10.5 x 13 mm	5°
SO460P	26 x 10.5 x 10 mm	8°
SO461P	26 x 10.5 x 11 mm	8°
SO462P	26 x 10.5 x 12 mm	8°
SO463P	26 x 10.5 x 13 mm	8°

All PROSPACE® XP implants are single sterile packed.

AESCULAP® PROSPACE® XP

C | IMPLANT & INSTRUMENT OVERVIEWV

SJ800/SJ801R – PROSPACE® XP

INSTRUMENTS	Article No.	Description	Recommended	Option
	FJ647R	Distractor, 7 mm	1	
	FJ648R	Distractor, 8 mm	1	
	FJ649R	Distractor, 9 mm	1	
	FJ650R	Distractor, 10 mm	1	
	FJ651R	Distractor, 11 mm	1	
	FJ652R	Distractor, 12 mm	1	
	FJ653R	Distractor, 13 mm	1	
	FJ655R	Distractor, 15 mm		1
	FJ657R	Distractor, 17 mm		1
	SN252R	Trial, 5°, 7 x 26 mm	1	
	SN253R	Trial, 5°, 8 x 26 mm	1	
	SN254R	Trial, 5°, 9 x 26 mm	1	
	SN255R	Trial, 5°, 10 x 26 mm	1	
	SN256R	Trial, 5°, 11 x 26 mm	1	
	SN257R	Trial, 5°, 12 x 26 mm	1	
	SN258R	Trial, 5°, 13 x 26 mm	1	
	SN260R	Trial, 5°, 15 x 26 mm		1
	SN262R	Trial, 5°, 17 x 26 mm		1
	FJ658R	Osteotome	1	
	FJ681R	Curette, straight	1	
	FJ684R	Bone rasp, straight	1	

Recommended container for SJ801R: JK442/JN442 and lid JK489.

INSTRUMENTS	Article No.	Description	Recommended	Option
	**SJ033R or alternatively SJ804R**	T-handle for distractors and trials	2	
	**FJ051R**	Nerve root retractor S	1	
	FJ052R	Nerve root retractor M	1	
	FJ053R	Nerve root retractor L	1	
	FJ054R	Nerve root retractor XL	1	
	**SN004R**	Packing block	1	
	**SN002R**	Inserter for PROSPACE® XP/ PROSPACE® PEEK	2	
	**SN003R**	Impactor	1	
	**FF913R**	Punch	1	
	SJ801R	Tray for preparation and implantation instruments	1	
	JH217R	Wide perforated basket lid	1	

Recommended container for SJ801R: JK442/JN442 and lid JK489.

AESCULAP® PROSPACE® XP

REFERENCES

(1) Tropiano P, Bronsard JJ, Louis C, Tallet JM, Sauget Y. Three column stabilisation through a posterior appraoch with a titanium PLASMAPORE® intervertebral block (PROSPACE®). Radiological and clinical study after 4 years. Rivista di Neuroradiologia. 1999;12(Suppl 1):89-94.

(2) Kroppenstedt S, Gulde M, Schonmayr R. Radiological comparison of instrumented posterior lumbar interbody fusion with one or two closed-box PLASMAPORE® coated titanium cages. Follow-up study over more than seven years. Spine. 2008;33(19):2083-8.

(3) Kreinest M, Schmahl D, Grutzner PA, Matschke S. Radiological Results and Clinical Patient Outcome After Implantation of a Hydraulic Expandable Vertebral Body Replacement following Traumatic Vertebral Fractures in the Thoracic and Lumbar Spine: A 3-Year Follow-Up. Spine (Phila Pa 1976). 2017 Apr 15;42(8):E482-E489.

(4) Takeuchi M, Yasuda M, Niwa A, Wakao N, Nakura T, Osuka K et al. PLASMAPORE®-coated titanium cervical cages induce more rapid and complete bone fusion after anterior cervical discectomy and fusion as compared to noncoated titanium cage. World Neurosurgery. 2014;82(3/4):519-22.

(5) Vanek P, Bradac O, Konopkova R, de Lacy P, Lacman J, Benes V. Treatment of thoracolumbar trauma by short-segment percutaneous transpedicular screw instrumentation: prospective comparative study with a minimum 2-year follow-up. J Neurosurg Spine. 2014;20:150-6.

(6) Beisse R. Endoscopic surgery on the thoracolumbar junction of the spine. Eur Spine J. 2006;15:687-704.

(7) Finger T, Bayerl S, Onken J, Czabanka M, Woitzik J, Vajkoczy P. Sacropelvic fixation versus fusion to the sacrum for spondylodesis in multilevel degenerative spine disease. Eur Spine J. 2014;23:1013-20.

(8) Mechanical testing of the AESCULAP® PROSPACE® XP implant evaluating shear resistance. Tuttlingen, 2013. The AESCULAP® PROSPACE® XP implant was tested in a shear force test test following internal standards to evaluate the risk of implant dislocation related to shear forces occurring in situ. For this test, a synthetic bone-equivalent polyurethane test block was used. A quasi-static shear force was applied to the implant. The implant was axially loaded during the whole test with a constant force to simulate a clinically relevant loading situation. Based on the maximum shear load obtained in the test, the risk of implant dislocation due to shear forces at a physiological load situation is unlikely to occur in the case of the AESCULAP® PROSPACE® XP implant.

(9) Kurtz SM, Devine JN. PEEK biomaterials in trauma, orthopedic, and spinal implants. Biomaterials 2007; 28(32):4845-69.

(10) Morrison C, Macnair R, MacDonald C, Wykman A, Goldie I, Grant MH. In vitro biocompatibility testing of polymers for orthopaedic implants using cultured fibroblasts and osteoblasts. Biomaterials 1995; 16(13):987-92.

(11) Invibio® Biomaterial Solutions. PEEK-OPTIMA® Natural - Typical Material Properties; 2013. Available from: URL: https://invibio.com/materials/peek-optima-natural.

(12) Chen Y, Wang X, Lu X, Yang L, Yang H, Yuan W et al. Comparison of titanium and polyetheretherketone (PEEK) cages in the surgical treatment of multilevel cervical spondylotic myelopathy: a prospective, randomized, control study with over 7-year follow-up. Eur Spine J 2013; 22(7):1539-46.

(13) Macnair R, Rodgers EH, MacDonald C, Wykman A, Goldie I, Grant MH. The response of primary rat and human osteoblasts and an immortalized rat osteoblast cell line to orthopaedic materials: comparative sensitivity of several toxicity indices. J Mater Sci Mater Med 1997; 8(2):105-11.

(14) Dr. Stuart Green, Keith Cartwright. An investigation into the effect of accelerated oxygen ageing on the properties of PEEK-OPTIMA®. March 2004. (B.DoCS-ID 21870982) Tensile, flex and impact specimens in PEEK-OPTIMA® were tested according to appropriate ISO standards (ISO 527, ISO 178 and ISO 180). A comparison was made between control PEEK-OPTIMA® and aged PEEK-OPTIMA® to investigate the effect of accele-

rated oxygen ageing on the material properties. Accelerated ageing was conducted exposing the specimens 40 days to 70°C oxygen at 5 bars pressure. The results show no significant effect on the mechanical properties of the PEEK polymer with the aged and control specimens showing similar values. The retention of good mechanical properties after the intense ageing cycle demonstrates that PEEK-OPTIMA® is very resistant to oxygen ageing.

(15) Cheng BC, Koduri S, Wing CA, Woolery N, Cook DJ, Spiro RC. Porous titanium-coated polyetheretherketone implants exhibit an improved bone-implant interface: an in vitro and in vivo biochemical, biomechanical, and histological study. MDER 2018; 11:391-402.

(16) Arregui R, Aso J, Martínez Quiñones J-V, Sebastián C, Consolini F, Aso Vizan A. Follow-up of a new titaniumcoated polyetheretherketone cage for the cervical spine. Orthop Rev (Pavia) 2020; 12(1).

(17) Rehnitz, Christoph, PD Dr. med. Radiological image evaluation of AESCULAP® interbody fusion devices, Heidelberg, 2019. CT and X-ray visualization of different AESCULAP® interbody fusion cages (full titanium, porous Ti6Al4V and PLASMAPORE$^{XP®}$ cages) was tested in a cadaver setup. A radiologist evaluated the implant visibility and the presence of artefacts that may limit the visualization of adjacent structures. Visualization and assessment of implant position was achieved in X-ray and CT for all tested cages. Minor artefacts were visible in CT reconstructions in the surrounding of porous Ti6Al4V and full titanium implants. Porous Ti6Al4V implants showed slightly fewer artefacts in CT in comparison to full titanium implants. The minor artefacts observed did not limit the assessment of the surrounding anatomical structures.

(18) Hasegawa T, Ushirozako H, Shigeto E, Ohba T, Oba H, Mukaiyama K et al. The Titanium-coated PEEK Cage Maintains Better Bone Fusion With the Endplate Than the PEEK Cage 6 Months After PLIF Surgery: A Multicenter, Prospective, Randomized Study. Spine (Phila Pa 1976) 2020; 45(15):E892-E902.

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